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UNITED STATES DISTRICT COURT

MIDDLE DISTRICT OF TENNESSEE

NASHVILLE DIVISION

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| SOPHIA LANE AND JASON LANE,<br><br>Plaintiffs,<br><br>v.<br><br>BOSTON SCIENTIFIC CORPORATION,<br><br>Defendant. | Case No. |

## COMPLAINT AND JURY DEMAND

COMES NOW, Sophia Lane and Jason Lane, as Plaintiffs herein and hereby file this Complaint, showing the Court as follows:

## PARTIES, JURISDICTION & VENUE

1. Plaintiffs are citizens of Murfreesboro, Tennessee.

2. Defendant Boston Scientific Corporation (Boston Scientific) is a Delaware corporation with its corporate headquarters in Massachusetts. All acts and omissions of Boston Scientific as described herein were done by its agents,

servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

3. Federal subject matter jurisdiction in this action is based upon 28 U.S.C. § 1332(a), in that there is complete diversity among Plaintiffs and Defendant and the amount in controversy exceeds $75,000.

4. Defendant has significant contacts with this federal judicial district such that they are subject to the personal jurisdiction of the court in this district.

5. A substantial part of the events and omissions giving rise to Plaintiffs' causes of action occurred in this federal judicial district. Pursuant to 28 U.S.C. § 1391(a), venue is proper in this district.

## FACTUAL BACKGROUND

6. Defendant Boston Scientific designed, manufactured, packaged, labeled, marketed, sold, and distributed the Boston Scientific Upsylon Y mesh pelvic mesh product ("the Product") which was implanted in Plaintiff, Sophia Lane.

7. Defendant's pelvic mesh products, including the Product, contain monofilament polypropylene mesh. Despite claims that polypropylene is inert, the scientific evidence shows that this material as implanted in Plaintiff, Sophia Lane is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with pelvic mesh products, including the Product. This negative response promotes inflammation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh. When mesh is inserted in the female body according to the manufacturers' instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.

8. Surgical mesh products have been used to repair abdominal hernias since the 1950s. In the 1970s, gynecologists began using surgical mesh products that were designed for hernia repair for abdominal repair to surgically repair prolapsed organs. In the 1990s, gynecologists began using this surgical mesh for the

surgical treatment of POP and SUI. Manufacturers, including Defendant, began to modify the mesh used in hernia repair to be used as products specifically intended to correct POP and/or SUI. Today, Defendant sells pelvic mesh "kits" which can include not only the surgical mesh, but also tissue fixation anchors and insertion tools. The Boston Scientific Upsylon Y mesh manufactured by Defendant is considered a Class II medical device.

9. Defendant sought and obtained FDA clearance to market Upsylon Y mesh under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) provides for marketing of a medical device if the device is deemed "substantially equivalent" to other predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is required, and no formal review for safety or efficacy was ever conducted by Boston Scientific with regard to Upsylon Y mesh.

10. On July 13, 2011, the FDA issued a Safety Communication wherein the FDA stated that "serious complications associated with surgical mesh for transvaginal repair of POP are not rare" (emphasis in the original).

11. The FDA Safety Communication also stated, "Mesh contraction (shrinkage) is a previously unidentified risk of transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA. Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain." (emphasis in original).

12. In a December 2011 Joint Committee Opinion, the American College of Obstetricians and Gynecologists (ACOG) and the American Urogynecologic Society (AUGS) also identified physical and mechanical changes to the mesh inside the body as a serious complication associated with vaginal mesh, stating:

> There are increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh . . . Some of these women will require surgical intervention to correct the condition, and some of the pain

appears to be intractable.

13. The ACOG/AUGS Joint Committee Opinion also recommended, among other things, that "[p]elvic organ prolapse vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk."

14. The injuries of Plaintiff, Sophia Lane, as will be more fully established in Discovery, are reported in the FDA Safety Communication and in the ACOG/AUGS Joint Committee Opinion.

15. The FDA Safety Communication further indicated that the benefits of using transvaginal mesh products instead of other feasible alternatives did not outweigh the associated risks. Specifically, the FDA Safety Communication stated: "it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk."

16. Contemporaneously with the Safety Communication, the FDA released a publication titled "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse" (the White Paper). In the White Paper, the FDA noted that the published, peer-reviewed literature demonstrates that "[p]atients who undergo POP repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh."

17. The FDA summarized its findings from its review of the adverse event reports and applicable literature stating that it "has NOT seen conclusive evidence that using transvaginally placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risk." (emphasis in original).

18. The FDA White Paper further stated that "these products are associated with serious adverse events . . . compounding the concerns regarding

adverse events are performance data that fail to demonstrate improved clinical benefit over traditional non-mesh repair."

19. In its White Paper, the FDA advises doctors to, *inter alia*, "[r]ecognize that in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications." The FDA concludes its White Paper by stating that it "has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse."

20. As is known to the Defendant, the risks associated with POP repair are the same as SUI repair. However, the data regarding the magnitude and frequency of these known risks are not as developed as the data on POP repair. The FDA recognized this, as demonstrated by its Section 522 Orders issued to manufacturers of pelvic mesh products used to treat SUI in January of 2012.

21. In September 2011, the FDA acknowledged the need for additional data and noted in "Surgical Mesh For Treatment of Women with Pelvic Organ Prolapse and Stress Urinary Incontinence" that the literature and information developing on SUI repair with mesh "indicates that serious complications can occur . . . [and] a case can be made for additional premarket and/or post market studies to better address the risk/benefit of all mesh products used for SUI."

22. Defendant did not, and has not, adequately studied the extent of the risks associated with Upsylon Y mesh. In January 2012, the FDA recognized the risk to women and mandated additional studies to further investigate these risks.

23. Defendant knew or should have known about Upsylon Y mesh's risks and complications identified in the FDA Safety Communication and the ACOG/AUGS Joint Committee Opinion.

24. Defendant knew or should have known that Upsylon Y mesh unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks.

25. The scientific evidence shows that the material from which Upsylon Y mesh are made is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with Upsylon Y mesh, including Plaintiff, Sophia Lane.

26. This negative response promotes inflammation of the pelvic tissue and contributes to the formation of severe adverse reactions to the mesh, such as those experienced by Plaintiff, Sophia Lane.

27. The FDA defines both "degradation" and "fragmentation" as "device problems" to which the FDA assigns a specific "device problem code." "Material Fragmentation" is defined as an "[i]ssue associated with small pieces of the device breaking off unexpectedly" and "degraded" as an "[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction." Upsylon Y mesh was unreasonably susceptible to degradation and fragmentation inside the body.

28. Upsylon Y mesh was unreasonably susceptible to shrinkage and contraction inside the body. Defendant should have known of this serious risk and warned physicians and patients.

29. Upsylon Y mesh was unreasonably susceptible to "creep" or the gradual elongation and deformation when subject to prolonged tension inside the body.

30. To this day, Upsylon Y mesh has been and continues to be marketed to the medical community and to patients as a safe, effective, reliable, medical device, implanted by safe and effective, minimally invasive surgical techniques, and as safer and more effective as compared to available feasible alternative treatments of pelvic organ prolapse and stress urinary incontinence, and other competing products.

31. A woman who elects to have her SUI or POP surgically treated has several options. SUI can be corrected through traditional abdominal surgery using

sutures to attach the urethra to a ligament in the pelvis (known as the "Burch procedure"). SUI can also be surgically addressed using synthetic materials placed under the urethra to provide support. POP can be corrected through abdominal or transvaginal surgery and using biologic, composite, or synthetic materials.

32. Defendant omitted and downplayed the risks, dangers, defects, and disadvantages of Upsylon Y mesh, and advertised, promoted, marketed, sold and distributed Upsylon Y mesh as a safe medical device when Defendant knew or should have known that Upsylon Y mesh was not safe for its intended purposes, and that Upsylon Y mesh would cause, and did cause, serious medical problems, and in some patients, including Plaintiff, Sophia Lane, catastrophic injuries. Further, while some of the problems associated with Upsylon Y mesh were made known to physicians, the magnitude and frequency of these problems were not disclosed and were hidden from physicians.

33. Contrary to Defendant's representations and marketing to the medical community and to the patients themselves, Upsylon Y mesh has high rates of failure, injury, and complications, fails to perform as intended, requires frequent and often debilitating re-operations, and has caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff, Sophia Lane, making them defective under the law.

34. The specific nature of Upsylon Y mesh's defects includes, but is not limited to, the following:

a. The use of polypropylene in Upsylon Y mesh and the immune reactions that result from such material, causing adverse reactions and injuries;

b. The design of Upsylon Y mesh to be inserted into and through an area of the body with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. Biomechanical issues with the design of Upsylon Y mesh, including, but not limited to, the propensity of Upsylon Y mesh to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. The use and design of arms and anchors in Upsylon Y mesh, which, when placed in the women, are likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region;

e. The propensity of Upsylon Y mesh for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. the inelasticity of Upsylon Y mesh, causing them to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking);

g. The propensity of Upsylon Y mesh for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

35. Upsylon Y mesh is also defective due to Defendant's failure to adequately warn or instruct Plaintiff, Sophia Lane and/or her health care providers of subjects including, but not limited to, the following:

a. Upsylon Y mesh's propensities to contract, retract, and/or shrink inside the body;

b. Upsylon Y mesh's propensities for degradation, fragmentation and/or creep;

c. Upsylon Y mesh's inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. The frequency and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from Upsylon Y mesh;

f. The risk of chronic infections resulting from Upsylon Y mesh;

g. The risk of permanent vaginal or pelvic scarring as a result of Upsylon Y mesh;

h. The risk of recurrent, intractable pelvic pain and other pain resulting from Upsylon Y mesh;

i. The need for corrective or revision surgery to adjust or remove Upsylon Y mesh;

j. The severity of complications that could arise as a result of implantation of Upsylon Y mesh;

k. The hazards associated with Upsylon Y mesh;

l. Upsylon Y mesh's defects described herein;

m. Treatment of pelvic organ prolapse and stress urinary incontinence with;

n. Upsylon Y mesh is no more effective than feasible available alternatives;

o. Treatment of pelvic organ prolapse and stress urinary incontinence with Upsylon Y mesh exposes patients to greater risk than feasible available alternatives;

p. Treatment of pelvic organ prolapse and stress urinary incontinence with Upsylon Y mesh makes future surgical repair more difficult than feasible available alternatives;

q. Use of Upsylon Y mesh puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

r. Removal of Upsylon Y mesh due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

s. Complete removal of Upsylon Y mesh may not be possible and may not result in complete resolution of the complications, including pain.

36. Defendant under reported and continues to underreport information about the propensity of Upsylon Y mesh to fail and cause injury and complications, and have made unfounded representations regarding the efficacy and safety of Upsylon Y mesh through various means and media.

37. Defendant failed to perform proper and adequate testing and research in order to determine and evaluate the nature, magnitude and frequency of the risks attendant to Upsylon Y mesh.

38. Defendant failed to design and establish a safe, effective procedure for removal of Upsylon Y mesh, or to determine if a safe, effective procedure for removal of Upsylon Y mesh exists.

39. Feasible and suitable alternatives to Upsylon Y mesh have existed at all times relevant that do not present the same frequency or severity of risks as do Upsylon Y mesh.

40. Upsylon Y mesh was at all times utilized and implanted in a manner foreseeable to Defendant, as Defendant generated the instructions for use, created the procedures for implanting the devices, and trained the implanting physician.

41. Defendant knowingly provided incomplete and insufficient training and information to physicians regarding the use of Upsylon Y mesh and the aftercare of patients implanted with Upsylon Y mesh.

42. Upsylon Y mesh implanted in Plaintiff, Sophia Lane was in the same or substantially similar condition as they were when they left Defendant's possession, and in the condition directed by and expected by Defendant.

43. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with Upsylon Y mesh include, but are not limited to, erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood

loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, and chronic pelvic pain.

44. In many cases, including Plaintiff, Sophia Lane's, women have been forced to undergo extensive medical treatment including, but not limited to, operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

45. The medical and scientific literature studying the effects of mesh products like Upsylon Y mesh, like that of the product implanted in Plaintiff, Sophia Lane , has examined each of these injuries, conditions, and complications, and has reported that they are causally related to mesh products.

46. Removal of contracted, eroded and/or infected mesh can require multiple surgical interventions for removal of mesh and results in scarring on fragile compromised pelvic tissue and muscles.

47. At all relevant times herein, Defendant continued to promote Upsylon Y mesh as safe and effective even when no clinical trials had been done supporting long- or short-term efficacy or safety.

48. In doing so, Defendant failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with Upsylon Y mesh, including the magnitude and frequency of these risks.

49. At all relevant times herein, Defendant failed to provide sufficient warnings and instructions that would have put Plaintiff, Sophia Lane and the general public on notice of the dangers and adverse effects caused by implantation of Upsylon Y mesh.

50. Upsylon Y mesh as designed, manufactured, distributed, sold and/or supplied by Defendant was defective as marketed due to inadequate warnings,

instructions, labeling and/or inadequate testing in the presence of Defendant's knowledge of lack of safety.

51. Plaintiff, SOPHIA LANE, was implanted with the Upsylon Y mesh on December 10, 2014, which was designed, manufactured, packaged, labeled, distributed and sold by Defendant.

52. The Upsylon Y mesh was intended to treat Plaintiff, Sophia Lane for vaginal wall prolapse, the use for which Defendant marketed the product.

53. Plaintiff, Sophia Lane's treating physicians implanted the Upsylon Y mesh properly and appropriately.

54. At all times material hereto, Defendant failed to comply or properly comply with state and Federal law in connection with the Upsylon Y mesh.

55. The risk of serious injuries was known or should have been known to Defendant, but in spite of these risks, Defendant continued to market the Upsylon Y mesh to physicians and patients, including Plaintiff, Sophia Lane, without adequate warnings.

56. Had Defendant properly disclosed the risks associated with the Upsylon Y mesh, Plaintiff, Sophia Lane would not have used it.

57. The injuries suffered by Plaintiff, Sophia Lane were caused by the wrongful acts, omissions, and fraudulent representations of Defendant.

58. As a result of having Upsylon Y mesh implanted in her, Plaintiff, Sophia Lane has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

## COUNT I: NEGLIGENCE

59. All previous paragraphs are hereby incorporated by reference as if fully set forth herein.

60. Defendant had a duty to individuals, including Plaintiff, Sophia Lane, to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling Upsylon Y mesh.

61. Defendant was negligent in failing to use reasonable care as described herein in designing, manufacturing, marketing, labeling, packaging and selling Upsylon Y mesh. Defendant breached its aforementioned duty by, among other things:

a. Failing to design Upsylon Y mesh so as to avoid an unreasonable risk of harm to women in whom Upsylon Y mesh were implanted, including Plaintiff, Sophia Lane ;

b. Failing to manufacture Upsylon Y mesh so as to avoid an unreasonable risk of harm to women in whom Upsylon Y mesh were implanted, including Plaintiff, Sophia Lane;

c. Failing to use reasonable care in the testing of Upsylon Y mesh so as to avoid an unreasonable risk of harm to women in whom Upsylon Y mesh were implanted, including Plaintiff, Sophia Lane;

d. Failing to use reasonable care in inspecting Upsylon Y mesh so as to avoid an unreasonable risk of harm to women in whom Upsylon Y mesh were implanted, including Plaintiff, Sophia Lane ;

e. Failing to use reasonable care in the training and instruction to physicians for the safe use of Upsylon Y mesh;

f. Failing to use reasonable care in studying Upsylon Y mesh to evaluate their safety and to determine the nature, magnitude, and frequency of serious, life threatening complications that were known or knowable; and

g. Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling Upsylon Y mesh.

62. The reasons that Defendant's negligence caused Upsylon Y mesh to be unreasonably dangerous and defective include, but are not limited to:

a. The use of polypropylene material in Upsylon Y mesh and the immune reaction that results from such material, causing adverse reactions and injuries;

b. The design of Upsylon Y mesh to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. Biomechanical issues with the design of Upsylon Y mesh, including, but not limited to, the propensity of Upsylon Y mesh to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. The use and design of arms and anchors in Upsylon Y mesh, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. The propensity of Upsylon Y mesh for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. The inelasticity of Upsylon Y mesh, causing them to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation);

g. The propensity of Upsylon Y mesh for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

63. Defendant also negligently failed to warn or instruct Plaintiff, Sophia Lane and/or her health care providers of subjects including, but not limited to, the following:

a. Upsylon Y mesh's propensities to contract, retract, and/or shrink inside the body;

b. Upsylon Y mesh's propensities for degradation, fragmentation and/or creep;

c. Upsylon Y mesh's inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. The rate and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from Upsylon Y mesh;

f. The risk of chronic infections resulting from Upsylon Y mesh;

g. The risk of permanent vaginal or pelvic scarring as a result of Upsylon Y mesh;

h. The risk of recurrent, intractable pelvic pain and other pain resulting from Upsylon Y mesh;

i. The need for corrective or revision surgery to adjust or remove Upsylon Y mesh;

j. The severity of complications that could arise as a result of implantation of Upsylon Y mesh;

k. The hazards associated with Upsylon Y mesh;

l. Upsylon Y mesh's defects described herein;

m. Treatment of pelvic organ prolapse and stress urinary incontinence with Upsylon Y mesh is no more effective than feasible available alternatives;

n. Treatment of pelvic organ prolapse and stress urinary incontinence with Upsylon Y mesh exposes patients to greater risk than feasible available alternatives;

o. Treatment of pelvic organ prolapse and stress urinary incontinence with Upsylon Y mesh makes future surgical repair more difficult than feasible available alternatives;

p. Use of Upsylon Y mesh puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. Removal of Upsylon Y mesh due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. Complete removal of Upsylon Y mesh may not be possible and may not result in complete resolution of the complications, including pain.

64. As a direct and proximate result of Defendant's negligence, Plaintiff, Sophia Lane has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

**COUNT II: STRICT LIABILITY – DESIGN DEFECT**

65. All previous paragraphs are hereby incorporated by reference as if fully set forth herein.

66. Upsylon Y mesh implanted in Plaintiff, Sophia Lane was not reasonably safe for its intended uses and was defective as described herein with respect to their design. As previously stated, Upsylon Y mesh's design defects include, but are not limited to:

a. The use of polypropylene material in Upsylon Y mesh and the immune reaction that results from such material, causing adverse reactions and injuries;

b. The design of Upsylon Y mesh to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. Biomechanical issues with the design of Upsylon Y mesh, including, but not limited to, the propensity of Upsylon Y mesh to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. The use and design of arms and anchors in Upsylon Y mesh, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. The propensity of Upsylon Y mesh for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. The inelasticity of Upsylon Y mesh, causing them to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation);

g. The propensity of Upsylon Y mesh for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions, and

i. The use of polypropylene material in Upsylon Y mesh and the failure to provide adequate directions for use (DFU) and training.

67. As a direct and proximate result of Upsylon Y mesh's aforementioned defects as described herein, Plaintiff, Sophia Lane has experienced significant mental and physical pain and suffering, has sustained permanent injury, has

undergone medical treatment and will likely undergo future medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

68. Defendant is strictly liable to Plaintiff, Sophia Lane for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

**COUNT III: STRICT LIABILITY – MANUFACTURING DEFECT**

69. All previous paragraphs are hereby incorporated by reference as if fully set forth herein.

70. Upsylon Y mesh implanted in Plaintiff, Sophia Lane was not reasonably safe for its intended uses and was defective as described herein as a matter of law with respect to their manufacture, in that it deviated materially from Defendant's design and manufacturing specifications in such a manner as to pose unreasonable risks of serious bodily harm to Plaintiff, Sophia Lane.

71. Defendant is strictly liable to Plaintiff, Sophia Lane for designing, manufacturing, marketing, labeling, packaging and selling defective products.

72. As a direct and proximate result of Upsylon Y mesh's aforementioned defects as described herein, Plaintiff, Sophia Lane has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and/or corrective surgery and hospitalization, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

**COUNT IV: STRICT LIABILITY – FAILURE TO WARN**

73. All previous paragraphs are hereby incorporated by reference as if fully set forth herein.

74. Upsylon Y mesh implanted in Plaintiff, Sophia Lane was not reasonably safe for its intended uses and was defective as described herein as a matter of law due to its lack of appropriate and necessary warnings. Specifically,

Defendant did not provide sufficient or adequate warnings regarding, among other subjects:

a. Upsylon Y mesh's propensities to contract, retract, and/or shrink inside the body;

b. Upsylon Y mesh's propensities for degradation, fragmentation, disintegration and/or creep;

c. Upsylon Y mesh's inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. The rate and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from Upsylon Y mesh;

f. The risk of chronic infections resulting from Upsylon Y mesh;

g. The risk of permanent vaginal or pelvic scarring as a result of Upsylon Y mesh;

h. The risk of recurrent, intractable pelvic pain and other pain resulting from Upsylon Y mesh;

i. The need for corrective or revision surgery to adjust or remove Upsylon Y mesh;

j. The severity of complications that could arise as a result of implantation of Upsylon Y mesh;

k. The hazards associated with Upsylon Y mesh;

l. Upsylon Y mesh's defects described herein;

m. Treatment of pelvic organ prolapse and stress urinary incontinence with Upsylon Y mesh is no more effective than feasible available alternatives;

n. Treatment of pelvic organ prolapse and stress urinary incontinence with Upsylon Y mesh exposes patients to greater risk than feasible available alternatives;

o. Treatment of pelvic organ prolapse and stress urinary incontinence with Upsylon Y mesh makes future surgical repair more difficult than feasible available alternatives;

p. Use of Upsylon Y mesh puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. Removal of Upsylon Y mesh due to complications may involve multiple surgeries and may significantly impair the patient's quality of life;

r. Complete removal of Upsylon Y mesh may not be possible and may not result in complete resolution of the complications, including pain; and

s. The nature, magnitude and frequency of complications that could arise as a result of implantation of Upsylon Y mesh.

75. Defendant is strictly liable to Plaintiff, Sophia Lane for designing, manufacturing, marketing, labeling, packaging and selling a defective product(s).

76. As a direct and proximate result of Upsylon Y mesh's aforementioned defects as described herein, Plaintiff, Sophia Lane has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

## COUNT V: BREACH OF EXPRESS WARRANTY

77. All previous paragraphs are hereby incorporated by reference as if fully set forth herein.

78. Defendant made assurances as described herein to the general public, hospitals and health care professionals that Upsylon Y mesh was safe and reasonably fit for its intended purposes.

79. Plaintiff, Sophia Lane and/or her healthcare provider chose Upsylon Y mesh based upon Defendant's warranties and representations as described herein regarding the safety and fitness of Upsylon Y mesh.

80. Plaintiff, Sophia Lane , individually and/or by and through her physician, reasonably relied upon Defendant's express warranties and guarantees that Upsylon Y mesh were safe, merchantable, and reasonably fit for their intended purposes.

81. Defendant breached these express warranties because Upsylon Y mesh implanted in Plaintiff, Sophia Lane was unreasonably dangerous and defective as described herein and not as Defendant had represented.

82. Defendant's breach of their express warranties resulted in the implantation of an unreasonably dangerous and defective product in the body of Plaintiff, Sophia Lane, placing said Plaintiff, Sophia Lane's health and safety in jeopardy.

83. As a direct and proximate result of Defendant's breach of the aforementioned express warranties, Plaintiff, Sophia Lane has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

**COUNT VI: BREACH OF IMPLIED WARRANTY**

84. All previous paragraphs are hereby incorporated by reference as if fully set forth herein.

85. Defendant impliedly warranted that Upsylon Y mesh was merchantable and was fit for the ordinary purposes for which it was intended.

86. When Upsylon Y mesh was implanted in Plaintiff, Sophia Lane to treat her pelvic organ prolapse and/or stress urinary incontinence, Upsylon Y mesh was being used for the ordinary purposes for which it was intended.

87. Plaintiff, Sophia Lane, individually and/or by and through her physician, relied upon Defendant's implied warranties of merchantability in consenting to have Upsylon Y mesh implanted in her.

88. Defendant breached its implied warranties of merchantability because Upsylon Y mesh implanted in Plaintiff, Sophia Lane was neither merchantable nor suited for its intended uses as warranted.

89. Defendant's breach of their implied warranties resulted in the implantation of unreasonably dangerous and defective products in the body of Plaintiff, Sophia Lane, placing said Plaintiff, Sophia Lane's health and safety in jeopardy.

90. As a direct and proximate result of Defendant's breach of the aforementioned implied warranties, Plaintiff, Sophia Lane has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

## COUNT VII: FRAUD

91. Plaintiff, Sophia Lanes hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

92. Defendant falsely and fraudulently represented to Plaintiff, Sophia Lane, her physicians, and to members of the general public that the aforesaid products were safe, effective, reliable, consistent, and better than the other similar pelvic repair procedures when used in the manner intended by the manufacturer.

The representations by said Defendant were, in fact, false. The true facts include, but are not limited to, that the aforesaid products were not safe to be used for treatment of urinary incontinence, pelvic organ prolapse, vaginal vault prolapse, or rectocele repair, and were, in fact, dangerous to the health and body of Plaintiff, Sophia Lane.

93. When the Defendant made these representations, it knew that they were false. Defendant made said representations with the intent to defraud and deceive Plaintiff, Sophia Lane, and with the intent to induce Plaintiff, Sophia Lane to act in the manner herein alleged, that is to use the aforementioned product for treatment of urinary incontinence, pelvic organ prolapse, vaginal vault prolapse, or rectocele repair.

94. At the time Defendant made the aforesaid representations, Plaintiff, Sophia Lane took the actions herein alleged; Plaintiff, Sophia Lane and her physicians were ignorant of the falsity of these representations and reasonably believed them to be true. In reliance upon said representations, Plaintiff, Sophia Lane was induced to, and did, use the aforesaid products as herein described. If Plaintiff, Sophia Lane had known the actual facts, she would not have taken such action. The reliance of Plaintiff, Sophia Lane and her physicians upon Defendant's representations were justified because said representations were made by individuals and entities that appeared to be in a position to know the true facts.

95. As a result of Defendant's fraud and deceit, Plaintiff, Sophia Lane was caused to sustain the herein described injuries and damages.

96. In doing the acts herein alleged, the Defendant acted with oppression, fraud, and malice, and Plaintiff, Sophia Lane is therefore entitled to punitive damages to deter Defendant and others from engaging in similar conduct in the future. Said wrongful conduct was done with advance knowledge, authorization and/or ratification of an officer, director and/or managing agent of Defendant.

97. Defendant's fraudulent concealment tolled the statute of limitations because only Defendant knew the true dangers associated with the use of the Pelvic Mesh Products as described herein. Defendant did not disclose this information to the Plaintiff, Sophia Lane, her health care providers the health care community and the general public. Without full knowledge of the dangers of the Pelvic Mesh Products Plaintiff, Sophia Lane could not, through reasonable diligence, discover that she had a valid claim.

98. As a direct and proximate result of Defendant's fraud, Plaintiff, Sophia Lane has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

**COUNT VIII: FRAUD BY CONCEALMENT**

99. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

100. At all times mentioned herein, Defendant had the duty and obligation to disclose to Plaintiff, Sophia Lane and to her physicians, the true facts concerning the Upsylon Y mesh that it was dangerous and defective, lacking efficacy for their purported use and lacking safety in normal use, and how likely it was to cause serious consequences to users including permanent and debilitating injuries. Defendant made the affirmative representations as set forth above to Plaintiff, Sophia Lane and her physicians and the general public prior to the date Upsylon Y mesh was implanted in Plaintiff, Sophia Lane, while concealing material facts.

101. At all times herein mentioned, Defendant, willfully, and maliciously concealed facts as set forth above from Plaintiff, Sophia Lane and her physicians, and therefore, Plaintiff, Sophia Lane, with the intent to defraud as herein alleged.

102. At all times herein mentioned, neither Plaintiff, Sophia Lane nor her physicians were aware of the facts set forth above, and had they been aware of said facts, they would not have acted as they did, that is, would not reasonably relied upon said representations of safety and efficacy and utilized the Upsylon Y mesh for correction of urinary incontinence, pelvic organ prolapse, vaginal vault prolapse and rectocele. Defendant's representations were a substantial factor in Plaintiff, Sophia Lane utilizing the Upsylon Y mesh for correction of her medical conditions.

103. As a result of the concealment of the facts set forth above, Plaintiff, Sophia Lane sustained injuries as hereinafter set forth.

104. In doing the actions herein alleged, Defendant acted with oppression, fraud, and malice and Plaintiff, Sophia Lane is therefore entitled to punitive damages in an amount reasonably related to Plaintiff, Sophia Lanes actual damages, and to Defendant's wealth, and sufficiently large to be an example to others, and to deter this Defendant, and others from engaging in similar conduct in the future.

105. Defendant's fraudulent concealment tolled the statute of limitations because only defendant knew the true dangers associated with the use of the Upsylon Y mesh as described herein. Defendant did not disclose this information to the Plaintiff, Sophia Lane, her health care providers the health care community and the general public. Without full knowledge of the dangers of the Upsylon Y mesh Plaintiff, Sophia Lane could not, through reasonable diligence, discover that she had a valid claim.

106. As a direct and proximate result of Defendant's fraud by concealment, Plaintiff, Sophia Lane has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

## COUNT IX: NEGLIGENT MISREPRESENTATION

107. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

108. At all relevant times herein, Defendant represented to Plaintiff, Sophia Lane and her physicians that the Upsylon Y mesh was safe to use to correct stress urinary incontinence, pelvic organ prolapse, vaginal vault prolapse and rectocele knowing that the Upsylon Y mesh was defective and capable of causing the injuries described herein.

109. The Defendant made the aforesaid representations with no reasonable ground for believing them to be true when Defendant's own data showed the Upsylon Y mesh to be defective and dangerous when used in the intended manner.

110. The aforesaid representations were made to the physicians prescribing the Upsylon Y mesh prior to the date it was prescribed to Plaintiff, Sophia Lane and used by her physicians with the intent that Plaintiff, Sophia Lane and her physicians rely upon such misrepresentations about the safety and efficacy of the Upsylon Y mesh. Plaintiff, Sophia Lane and her physicians did reasonably rely upon such representations that the aforesaid products were safe for use to correct stress urinary incontinence, pelvic organ prolapse, vaginal vault prolapse and rectocele.

111. The representations by said Defendant to Plaintiff, Sophia Lane were false, and thereby caused Plaintiff, Sophia Lane's injuries described herein.

112. Defendant's fraudulent concealment tolled the statute of limitations because only Defendant knew the true dangers associated with the use of the Upsylon Y mesh as described herein. Defendant did not disclose this information to the Plaintiff, Sophia Lane, her health care providers the health care community and the general public. Without full knowledge of the dangers of the Upsylon Y mesh Plaintiff, Sophia Lane could not, through reasonable diligence, discover that she had a valid claim.

113. As a direct and proximate result of Defendant's breach of the aforementioned negligent misrepresentations, Plaintiff, Sophia Lane has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

## COUNT X: DISCOVERY RULE, TOLLING AND FRAUDULENT CONCEALMENT

114. All previous paragraphs are hereby incorporated by reference as if fully set forth herein.

115. Plaintiffs assert all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, and fraudulent concealment.

116. Plaintiffs plead that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiffs knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiff, Sophia Lane had been injured, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

117. Despite diligent investigation by Plaintiff, Sophia Lane into the cause of her injuries, including consultations with Plaintiff, Sophia Lane's medical providers, the nature of Plaintiff, Sophia Lane's injuries and damages, and her relationship to Upsylon Y mesh was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff, Sophia Lane's claims. Therefore, under appropriate application of the discovery rule, Plaintiffs' suit was filed well within the applicable statutory limitations period.

118. The running of the statute of limitations in this cause is tolled due to equitable tolling. Defendant is estopped from asserting a statute of limitations defense due to Defendant's fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiff, Sophia Lane and Plaintiff, Sophia Lane's physicians of the true risks associated with Upsylon Y mesh. As a result of Defendant's fraudulent concealment, Plaintiff, Sophia Lane and Plaintiff, Sophia Lane's physicians were unaware, and could not have known or have learned through reasonable diligence that Plaintiff, Sophia Lane had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendant.

**COUNT XI: PUNITIVE DAMAGES**

119. All previous paragraphs are hereby incorporated by reference as if fully set forth herein.

120. Defendant sold Upsylon Y mesh to the healthcare providers of the Plaintiff, Sophia Lane and other healthcare providers in the state of implantation and throughout the United States without doing adequate testing to ensure that Upsylon Y mesh was reasonably safe for implantation in the female pelvic area.

121. Defendant sold Upsylon Y mesh to Plaintiff, Sophia Lane's health care providers and other health care providers in the state of implantation and throughout the United States in spite of its knowledge that Upsylon Y mesh can shrink, disintegrate and/or degrade inside the body, and cause the other problems heretofore set forth in this complaint, thereby causing severe and debilitating injuries suffered by the Plaintiff, Sophia Lane and numerous other women.

122. Defendant ignored reports from patients and health care providers throughout the United States and elsewhere of Upsylon Y mesh's failures to perform as intended, which lead to the severe and debilitating injuries suffered by the Plaintiff, Sophia Lane and numerous other women. Rather than doing adequate testing to determine the cause of these injuries, or to rule out Upsylon Y mesh's

designs or the processes by which Upsylon Y mesh are manufactured as the cause of these injuries, Defendant chose instead to continue to market and sell Upsylon Y mesh as safe and effective.

123. Defendant knew Upsylon Y mesh was unreasonably dangerous in light of its risks of failure, pain and suffering, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the use of Upsylon Y mesh, as well as other severe and personal injuries which were permanent and lasting in nature.

124. Defendant withheld material information from the medical community and the public in general, including Plaintiff, Sophia Lane, regarding the safety and efficacy of Upsylon Y mesh.

125. Defendant knew and recklessly disregarded the fact that Upsylon Y mesh caused debilitating and potentially life altering complications with greater frequency than feasible alternative methods and/or products used to treat pelvic organ prolapse and stress urinary incontinence.

126. Defendant misstated and misrepresented data and continues to misrepresent data so as to minimize the perceived risk of injuries caused by Upsylon Y mesh.

127. Notwithstanding the foregoing, Defendant continues to aggressively market Upsylon Y mesh to consumers, without disclosing the true risks associated with Upsylon Y mesh.

128. Defendant knew of Upsylon Y mesh's defective and unreasonably dangerous nature, but continued to mislead physicians and patients and to manufacture, market, distribute, and sell Upsylon Y mesh so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, Sophia Lane.

129. Defendant continues to conceal and/or fail to disclose to the public, including the Plaintiff, Sophia Lane, the serious complications associated with the

use of Upsylon Y mesh to ensure continued and increased sales of Upsylon Y mesh.

130. Defendant's conduct as described herein shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which raises the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendant and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

- Compensatory damages to Plaintiffs for past, present, and future damages, including but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiff, Sophia Lane, emotional distress, mental anguish, physical disfigurement and impairment; health and medical care costs, together with pre- and post-judgment interest and costs as provided by law;
- Restitution and disgorgement of profits;
- Reasonable attorneys' fees;
- The costs of these proceedings;
- All ascertainable economic damages;
- Punitive damages; and
- Such other and further relief as this Court deems just and proper.

## COUNT XII: LOSS OF CONSORTIUM

131. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further alleges as follows.

132. Plaintiff, Jason Lane, is lawfully married to Plaintiff, Sophia Lane, and, as such, is entitled to the services, society and companionship of his spouse.

133. As a direct and proximate result of the foregoing, Plaintiff, Jason Lane was, and has been, deprived of the comfort and enjoyment of the services, society and companionship of his spouse, Plaintiff, Sophia Lane, has suffered and will continue to suffer economic loss, and has otherwise been emotionally and economically injured. Plaintiff, Jason Lane's injuries and damages are permanent and will continue into the future. Plaintiffs seek actual and punitive damages from all Defendants as alleged herein.

WHEREFORE, Plaintiffs pray for judgment in Count XII against Defendants for damages in excess of Seventy-Five Thousand Dollars ($75,000.00), which is fair and reasonable, costs herein expended, punitive damages to punish and deter any such conduct in the future and such other relief as the Court deems just and proper under the circumstances.

**PLAINTIFFS DEMAND A TRIAL BY JURY.**

Dated: September 18, 2018

Respectfully submitted,

LIEFF CABRASER HEIMANN & BERNSTEIN, LLP

By: */s/ Kenneth S. Byrd*
Kenneth S. Byrd
Attorneys for Plaintiff